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**APPLICATION NUMBER: 60/443,822** 

FILING DATE: January 30, 2003

RELATED PCT APPLICATION NUMBER: PCT/US04/02723

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Certifying Officer

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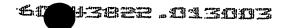
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Theodore				ARONE		(City and either State or Foreign Country)  West Palm Beach, Florida				
Additional inventors are being named			on the1	separately nu	nbered sheets	attached hereto				
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				Attorney Docket No. 44669-0004						
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Name (Print/Type) Jordan A. Newmark, Esq.			(A	Registration No. (Attorney/Agent)			304	Telephone 954-527-6243		
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**COVER SHEET** 

Re:

New U.S. Provisional Patent Application

Title: ARTICULATED SUPPORT ASSEMBLY

Inventors: Theodore T. TARONE and Mario LaCASSE Attorney Docket No. 44669-0004

Sir:

Enclosed are the following documents for filing:

[X] Fee Transmittal Form, in duplicate

[X] Provisional Application with Patent Cover Sheet

[X] Specification – 14 pages

[X] Drawings – 2 Sheets (Figs. 1-2)

[X] Post card for return receipt of documents

These documents enclosed and referenced herein are being submitted under the Express Mail filing provisions, 37 CFR 1.10, and a filing date corresponding to the date of deposit is respectfully requested.

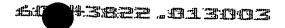
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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE PROVISIONAL PATENT APPLICATION

Title: ARTICULATED SUPPORT ASSEMBLY

Inventors: Theodore T. TARONE

Mario LaCASSE

#### TECHNICAL FIELD

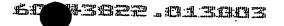
This invention relates generally to support assemblies. More particularly, the present invention relates to an adjustable support assembly used to support a stepper apparatus and precision medical instruments for use in surgery.

#### BACKGROUND OF THE INVENTION

As the medical field further advances, surgical procedures requiring precise positioning of monitoring and surgical tools become necessary. Radiologists perform numerous guided biopsies using ultrasound and computer aided tomography ("CAT") scanning techniques, magnetic resonance imaging techniques and fluoroscopic techniques. Biopsies and other procedures are performed using a variety of needle-like instruments.

For example, one currently widely applied and popular method the treatment for of prostate cancer : is brachytherapy, a form of cancer treatment in which a radioactive energy source is placed into or adjacent to a malignant tumor. Generally, brachytherapy can be divided into two categories: high dose rate (HDR) and low dose rate In HDR brachytherapy, a radioactive energy source with high activity is placed into or adjacent to the malignant tumor for а predefined period of time. Conversely, LDR brachytherapy entails the placement of a low activity radioactive energy source into or adjacent to the malignant tumor for an indeterminate period of time.

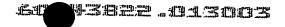
In LDR brachytherapy, radioactive isotopes are used as the radioactive energy sources. Some of the more common radioactive isotopes used in LDR brachytherapy include Iodine-125, Palladium-103, Gold-198, Ytterbium-169, Iridium-192. These isotopes are typically packaged in a housing constructed of a lightweight and durable material, such as titanium, and are commonly referred to as isotope The dimensions of the isotope seeds can seeds. extremely variable both in diameter and in length. The radioactive isotopes commonly used in LDR brachytherapy are selected for their low energy and relatively short half-Low energy sources provide for a limited tissue life.



penetration by the emitted radiation, so that the radiation's effects are limited to the tumor without substantially affecting adjacent normal tissue. A short half-life is advantageous in that the dose of radiation that is delivered depletes in a reasonably short period of time.

The area of therapeutic effect for Iodine-125 and Palladium-103 is limited to a sphere approximately 1 cm in diameter around the isotope seed. As a result, a three-dimensional array of isotope seeds is commonly used to treat a tumor. In LDR brachytherapy of prostate cancer, a multitude of isotope seeds is typically used. Since solid tumors, like those found in prostate cancer, are perceived to be diffuse, the entire organ is targeted for therapy.

In order to place isotope seeds into the aforementioned three-dimensional array, needles, using a two-dimensional grid pattern in · conjunction longitudinal spacing, can deliver isotope seeds. dimensional grid is frequently defined by a needle guide, called a template. The template is provided with a plurality of holes: that provide guidance for the longitudinal progression of the needles, thus insuring their desired two-dimensional position within the tumor. After the two-dimensional needle array is positioned within



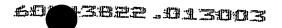
the tumor, the isotope seeds are deposited along the longitudinal axis of each needle.

Presently, there are many commercially available devices for holding, manipulating and stabilizing the numerous commercially available needle holders designed for use in brachytherapy procedures. In general, these devices have not overcome the same basic limitation; they are "post-insertion" probe fixation devices where the probe is first inserted into the body and then affixed to a stand. This necessitates a subsequent reorientation of the probe with regard to the insertion cavity, thereby wasting valuable time in obtaining the desired probe orientation.

In an attempt to remedy these shortcomings, certain pre-insertion fixation devices have been developed. In these devices, the probe is first affixed to a stand. The combination of the fine adjustment mechanism with the probe affixed is then released to the free omni-directional mode to enhance insertion of the probe into the body of the patient. For brachytherapy, for example, the probe is manually inserted into the rectum and, once the desired orientation is achieved, as viewed and confirmed by the monitored ultrasound images, the device is then set in a fixed mode.

Many currently available devices provide movement along several axes, however such movement risks a loss of orientation in other axes during adjustment. Additionally, the fine adjustment of such devices is quite limited. Moreover, such devices are unwieldy and tend to either be heavy and/or broad-based to achieve floor stand based stability or spatially cumbersome table-mounted structures that tend to obstruct the user's movements and patient access. The known stabilizer assemblies, including those used to support devices for brachytherapy, are often difficult to manipulate by the physician, unreliable in operation, and are susceptible to mechanical problems. Furthermore, reliable and convenient locking of the support apparatus in a desired position is frequently challenging, and the range and variety of movement possible for many stabilizers is not satisfactory.

Thus, there remains a need for a new stabilizer which is reliable and convenient to operate, readily lockable in a desired position, easily attachable to a variety of mounting structures, and in particular is capable of moving smoothly and precisely for improved holding, manipulation and stabilizing devices for use in a variety of procedures. In addition, there are numerous other medical procedures



and non-medical applications where enhanced holding, manipulation and/or stabilizing of devices can be helpful.

#### SUMMARY OF THE INVENTION ......

The present invention eliminates the above-mentioned needs for a protection device by providing an articulated support assembly.

In accordance with the present invention, there is provided an articulated support assembly comprising a stepping head clamping lock, a lockable support assembly connected to said stepping head clamping lock and selectively releasably connectable to a stationary object for allowing multi-planar orthogonal manipulation of a device into a position with respect a plane of said stationary object, and a plurality of joints connected to said lockable support assembly that allows multi-planar orthogonal movement.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a perspective view illustration of the preferred embodiment of the present invention.

FIGURE 2 is a perspective view illustration of the preferred embodiment of the present invention of FIGURE 1.

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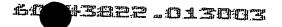


#### DETAILED DESCRIPTION OF THE INVENTION

Referring now to Fig. 1, a preferred embodiment of the present invention is illustrated as articulated support assembly 10. Articulated support assembly 10 includes stepping head clamping lock 12, lockable support assembly 14, and a plurality of joints 16a, 16b, 18a, 18b, 29a, and 29b.

As illustrated in Fig. 1, stepping head clamping lock 12 secures removable stepping head assembly 20 to lockable support assembly 14. As is shown in Fig. 2, removable stepping head assembly 20 slides into a stepping head clamp 13 in order to be secured in position. Stepping head clamp 13 is connected to lockable support assembly 14, thereby facilitating the engagement of removable stepping head assembly 20 to lockable support assembly 14. Once removable stepping head assembly 20 is placed in the appropriate position, stepping head clamping lock 12 secures the engagement of removable stepping head assembly 20 to lockable support assembly 14.

Removable stepping head assembly 20 can support a number of devices, including, but not limited to medical devices, such as brachytherapy devices, laser devices, ultrasonic devices, x-ray devices, and lighting devices. In the preferred embodiment of the present invention,



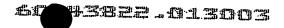
medical device 40 is a brachytherapy device for inserting radioactive isotope seeds and non-radioactive spacers via an elongated needle into a patient.

In order to effectively insert radioactive isotope seeds and non-radioactive spacers through medical device 40, articulated support assemblý 10 is preferably selectively releasably connectable to a stationary object for allowing multi-planar orthogonal manipulation of the medical device into a position with respect a plane of the stationary object. The stationary object is preferably a medical table, but other stationary objects, such as walls, floors, ceilings, counters, and the like are contemplated. Lockable support assembly 14 includes at least one clamp .32a or 32b for securing lockable support assembly 14 to the stationary object. Stationary object lock 30 is operated .. by the user to tighten the secure engagement between lockable support assembly 14 and the stationary object once lockable support assembly 14 is secured to the stationary object (not shown).

Once lockable support assembly 14 is fully secured to the stationary object, support arms 22a and 22b, which can be formed from the same structure, as clams 32a and 32b, respectively, permit movement through a first plane substantially parallel to a first plane of the stationary

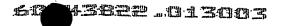
object. Support arms 22a and 22b include joint articulation points 16a and 16b. Joint articulation points 16a and 16b allow for arms 24a and 24b to be fitted The connection between joint articulation points therein. 16a and 16b and arms 24a and 24b can form any one of a number of joint arrangements, however, it is preferred that arrangement joint move within the first substantially parallel to the first plane of the stationary object.

When arms 24a and 24b are in their desired positions, horizontal position locks 28a and 28b are operated by the user to tighten and prevent movement between arms 24a and 24b and joint articulation points 18a and 18b. This will allow articulated support assembly 10 to be held within one position with respect to the first plane substantially parallel to the first plane of the stationary object. Joint articulation points 18a and 18b also permit movement of articulated support assembly 10 within a second plane substantially parallel to a second plane of the stationary In the preferred embodiment of the present invention, the second plane is substantially perpendicular to the first plane. For example, if the first plane is the horizontal plane of the stationary object; the second plane is the corresponding substantially perpendicular vertical



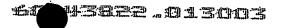
plane. Arms 27a and 27b engage joint articulation points 18a and 18b and move in directions perpendicular to the directions moved by arms 24a and 24b. Upon being placed in their desired positions, arms 24a and 24b are locked into place by vertical position locks 26a and 26b. Vertical position locks 26a and 26b are operated by the user to tighten and prevent movement between arms 27a and 27b and lockable support assembly 14. This will allow lockable support assembly 14 to be held within one position with respect to the second plane substantially parallel to the second plane of the stationary object and substantially perpendicular to the first plane of the stationary object.

Lockable support assembly 14 can then be secured in position by tightening joint articulation points 29a and 29b. The tightening of joint articulation points 29a and 29b is accomplished by engaging assembly lock 25, thus preventing any undesired movement by lockable support assembly 14. Removable stepping head assembly 20 can be finely adjusted for positioning of device 38 fine adjustment assembly 34. Moreover, the pitch of removable stepping head assembly 20, and therefore device 38, can be adjusted as well. Once the desired pitch of removable stepping head assembly 20 is located, the user can then



engage pitch lock 36 to prevent movement of removable stepping head assembly 20 from the desired pitch.

Although only a few exemplary embodiments of the present invention have been described in detail above, those skilled in the art will readily appreciate that numerous modifications are to the exemplary embodiments are possible without materially departing from the novel teachings and advantages of this invention. Accordingly, all such modifications are intended to be included within the scope of this invention as defined in the following numbered paragraphs.



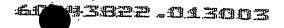
A further description of the preferred embodiment is detailed in the numbered paragraphs as follows:

1. An articulated support assembly comprising:
a stepping head clamping lock;

a lockable support assembly connected to said stepping head clamping lock and selectively releasably connectable to a stationary object for allowing multi-planar orthogonal manipulation of a device into a position with respect a plane of said stationary object; and

a plurality of joints connected to said lockable support assembly that allows multi-planar orthogonal movement.

- 2. The assembly according to paragraph 1 further comprising a removable stepping head assembly.
- 3. The assembly according to paragraph 1 wherein said lockable support assembly includes at least one support arm.
- 4. The assembly according to paragraph 3 wherein said at least one support arm is connected to a joint of said plurality of joints.



- 5. The assembly according to paragraph 4 wherein said at least one support arm includes at least one position lock.
- 6. The assembly according to paragraph 5 wherein said at least one position lock prevents vertical movement when engaged.
- 7. The assembly according to paragraph 5 wherein said at least one position lock prevents horizontal movement when engaged.
- 8. The assembly according to paragraph 5 wherein said at least one position lock prevents movement of when engaged.
- 9. The assembly according to paragraph 4 wherein said at least one support arm includes at least one stationary object lock.
- 10. The assembly according to paragraph 9 wherein said at least one stationary object lock is a clamp lock.
- 11. The assembly according to paragraph 2 wherein said removable stepping head assembly further comprises a fine adjustment assembly.

12. The assembly according to paragraph 2 wherein said removable stepping head assembly further comprises a pitch lock.

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- 13. The assembly according to paragraph 2 wherein said removable stepping head assembly receives said device.
- . 14. The assembly according to paragraph 13 wherein said device is a medical device.

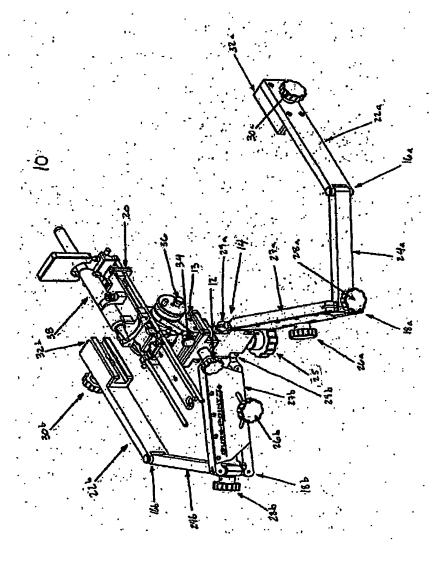


FIGURE 1

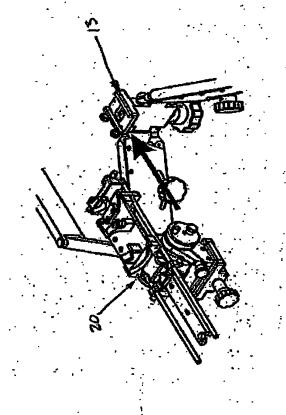


FIGURE 2

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